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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,600	10/25/2000	Thomas A. Peterson	P04716US2(ISURF 2330)	6794

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 10/16/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/696,600

Applicant(s)

PETERSON ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 11-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 18-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-4 and 18-22 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the groups are related by a single method and should not require separate searches. This is not found persuasive because the different methods yield different products. However, during the course of examination it was determined that examination of claims 5-10 and 23 would not impose an undue burden, and therefore Group II has been rejoined with Group I. Claims 1-10, 18-23, and new claims 24-35 have been examined in this Office action.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the instant application was filed more than 12 months after the filing of the provisional application, and the priority is denied.

Drawings

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

3. This information replaces the information of how to effect drawing changes that is on the backside of the accompanying PTO-948.

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New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Claim Objections

4. Claims 6, 7, 9, 20, 22, and 23 are objected to because of the following informalities: In claims 6, 7, 22, and 23: line 1 of the claims, "A" should be --The--. Appropriate correction is required.

In claims 19 and 20, line 3, the article "a" should be --the--.

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-10 and 18-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 5, and 8: the recitation “making available to the plant a transposase” in lines 3-4 of claim 1, line 6 of claim 5, and lines 6-7 of claim 8 render them indefinite. It is not exactly clear what is meant by making something “available” to a plant, especially since the recombination event of the claimed method is occurring within the cells of the plant. It is suggested that the recitation be replaced with --expressing a transposase within the plant--.

In claim 5: the recitation “a functional gene” in lines 7-8 renders the claim indefinite. It is not clear if the gene of the recitation is referring to the same functional gene mentioned in line 5 or a different one. It is suggested that the article “a” in line 7 be replaced with --said--.

In claims 6, 9, 25, 33, and 35: the recitation “commercially enhancing a biosynthetic pathway” renders the claim indefinite. It is not clear what is meant by the recitation. The metes and bounds of the claim are not clear.

In claim 8: the claim recites the limitation “the transposase” in lines 6-7. There is insufficient antecedent basis for this limitation in the claim.

Further in claim 8: the claim is written in a confusing manner. Lines 1-5 indicate that transcription/translation of a gene will occur when the overlapping sequences have recombined to result in a gene. However, line 5 indicates that the transposase is made available “subsequently”, after the recombination event. This is confusing, since the transposase is

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required for the recombination event. The recitation “A method to induce transcription and/or translation of a gene” in line 1 also renders the claim indefinite. The promoter would have been recognized by RNA polymerase regardless of the recombination event. The recombination event itself does not have anything to do with the induction of transcription or translation. It is also inaccurate to state that a gene is translated. The recitation “a maize Ds element containing overlapping sequences having homologous regions” in lines 2-4 of claim 8 also renders the claims indefinite. The specification and Figure 1 indicate that the overlapping homologous regions are shared by the fragments of a gene that are combined by the recombination event. The gene fragments are not internal to the Ds element, but rather flank it.

In claim 18: the recitation “introduction of a maize transposase” in line 2 renders the claim indefinite. It is not clear if the maize transposase is being inserted into the construct. If it is not, it is not clear what the transposase is being introduced into. It is suggested that the recitation “upon introduction” be replaced with --in the presence--. Further, it is suggested that the recitation --, said construct—be inserted in line 2 before “comprising”, so that the claim unambiguously indicates that the repeat sequences are within the construct.

In claims 19 and 20: the recitation “a maize transposase comprising a maize recombination construct” in lines 2-4 renders the claim indefinite. The recitation appears to indicate that the transposase comprises a nucleic acid construct. It is suggested that the recitation --, said composition of matter --be inserted into line 3 after “transposase.”

In claim 20: the recitation “a maize recombination construct of claim 18 in a plant” renders the claim indefinite. It is not clear what this recitation is referring to.

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In claims 19, 20, 22, and 23: the recitation, "composition of matter", renders the claims indefinite. DNA molecules can be induced to undergo homologous recombination. However, it is not clear what else is encompassed by the recitation, as the claims indicate that it is the composition of matter that undergoes recombination. The metes and bounds of the claims are not clear. The claims also broaden the scope of parent claim 18, which is directed to a recombination construct. Claims 19, 20, 22, and 23, however, are drawn to any composition of matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 27, 28, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Shalev et al. (Genetics, July 1997, Vol. 146, pages 1143-1151).

The claims are broadly drawn towards any method to induce homologous recombination in a plant, comprising introducing a recombination construct to the plant and making available to the plant a transposase to induce homologous recombination; or wherein the recombination construct comprises a maize Ds element and the transposase is of maize origin; or wherein the recombination construct comprises direct repeats proximal to the Ds element; or wherein the transposase is Ac; or wherein the plant is a dicot.

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Shalev et al. teach an assay for homologous recombination induced by the maize Ac transposase in transgenic tobacco plants. The plants were transformed with constructs containing the maize Ds element flanked by direct repeats. Recombination induced by Ac resulted in the combination of GUS deletion mutants to yield an intact, functional GUS gene (pages 1144-1146).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-10 and 18-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swoboda et al. (EMBO, 1994, Vol. 13, pages 484-489) in view of Shalev et al. (Genetics, July 1997, Vol. 146, pages 1143-1151), Holtorf et al. (Plant Mol. Biol., 1995, Vol. 29, pages 637-646), Hain et al. (Nature, 1993, Vol. 361, pages 153-156), and Fromm et al. (Biotechnology, 1990, vol. 8, pages 833-839).

The claims are broadly drawn towards a method to induce homologous recombination in a plant, comprising introducing any recombination construct to the plant, and making available any transposase, or wherein the transposase is of maize origin and said construct comprises the maize Ds element; or a method to construct a functional gene in a plant, comprising introducing a recombination construct in a plant having overlapping, homologous regions which recombine to yield a functional gene; or a method to induce transcription/translation or a gene in a plant,

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comprising introducing to the plant a maize Ds element containing overlapping sequences having homologous regions, which sequences, when recombined, result in a gene; any recombination construct which can be induced to undergo homologous recombination upon introduction of a maize transposase comprising direct repeat sequences proximal to a Ds element and an agronomically significant gene internal to the direct repeats; and any compositions of matter which can be induced to undergo homologous recombination upon introduction of a maize transposase comprising said recombination construct; or said recombination construct wherein the transposase gene is under the control of an inducible promoter; or said composition of matter which further comprises a gene internal to said direct repeat sequences.

Swoboda et al. teach intrachromosomal homologous recombination in plants, comprising recombination between gene fragments, in a recombination construct, sharing overlapping regions, and wherein a hygromycin coding sequence between the gene fragments is excised, resulting in an intact, functional GUS gene, from which GUS mRNA was transcribed. The overlapping regions form direct repeats. (pages 484-485, 488-489).

Swoboda et al. do not teach homologous recombination induced by a transposase, or an inducible promoter, disease resistance genes, or transgenic maize plants.

Shalev et al. is discussed above. Shalev et al. also discuss that double-stranded breaks in DNA induce homologous recombination, that Ac-mediated excision induced recombination between direct repeats flanking the excision site by at least two orders of magnitude (pages 1143, 1144, 1147-1150).

Holtorf et al. teach a heat-inducible heat shock promoter (pages 639-640).

Hain et al. teach enhanced disease resistance against fungal infection in transgenic tobacco plants conferred by a grape stilbene synthase gene (pages 153-156).

Fromm et al. teach the production of transgenic maize plants (pages 833-836).

It would have been obvious and within the scope of one of ordinary skill in the art at the time the invention was made to modify the homologous recombination method of Swoboda et al. by inducing the recombination event with a transposase system, such as the Ac/Ds system taught by Shalev et al. It would have been obvious, given the teachings of Shalev et al., that placement of the Ds element between the "GU" and "US" fragments of the construct of Swoboda et al. would have induced recombination between the overlapping sequences of the "GU" and "US" fragments to yield an intact GUS coding sequence. One would have been motivated to use a transposase to induce recombination, given the teaching of Shalev et al. that the recombination occurs more frequently when induced by Ac. It would also have been obvious to include the Ac transposase coding sequence on the recombination construct, and to place it under the control of an inducible promoter, for example the heat shock promoter of Holtorf et al. It was also obvious that inclusion of the Ac transposase coding sequence on the recombination construct would have eliminated the need to introduce the transposase in a separate step. One would also obviously have been motivated to regulate the expression of the transposase, to control the timing and/or tissue location of the recombination event. It also would have been obvious to replace the sequences encoding the GUS gene fragments with fragments of any other gene of interest, for example the stilbene synthase gene taught by Hain et al., which confers disease resistance against fungal infection. Alternatively, one may also have replaced the hygromycin coding sequence of Swoboda et al. with any other gene of interest. One would have been motivated to make such

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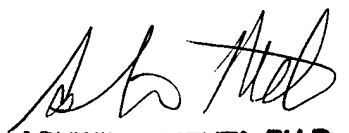
gene replacements depending upon the particular use of the method and the desired effect of the gene resulting from the recombination event. It also would have been obvious to introduce the recombination construct into any plant, for example the maize plants, using the transformation method taught by Fromm et al. One would obviously have been motivated to introduce the construct into any plant of interest, depending on the desired end.

8. Claims 1-10 and 18-35 are rejected, and claims 11-17 are withdrawn from consideration.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

October 14, 2002


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER